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Janie Miller
Secretary

To: Kentucky Vaccine Program (KVP) Providers who receive ROTARIX® vaccine from KVP

From: Alicia Tindall, RN, BS

Date: May 28, 2010

Subject: Recommendation by CDC and FDA to resume use of ROTARIX brand rotavirus vaccine

The Kentucky Immunization Program was notified on May 14, 2010, that the FDA recommended resuming the use of ROTARIX brand rotavirus vaccine (RV1) manufactured by GlaxoSmithKline after having temporarily recommended that clinicians suspend the use of ROTARIX vaccine in March 2010. Furthermore, the FDA recommends that clinicians continue the use of RotaTeq rotavirus vaccine (RV5) manufactured by Merck.

Porcine circovirus has been found in both ROTARIX and RotaTeq rotavirus vaccines. Even though this virus is not known to cause illness in humans or other animals, it was not previously known to be present in either vaccine. The FDA reached this decision to resume use of ROTARIX vaccine based on evaluation of information from laboratory results from the manufacturers as well as the FDA's laboratories, a review of scientific literature, and input from scientific and health experts.

At this time, the Kentucky Immunization Program is requesting that providers resume the use of ROTARIX vaccine and continue the use of RotaTeq vaccine per ACIP guidelines. CDC is resuming distribution of ROTARIX vaccine.

CDC is not recommending the recall or revaccination of patients who have received ROTARIX vaccine, and no testing is recommended for patients who have received ROTARIX vaccine. Parents of children who have received the vaccine should be reassured that this virus is not known to infect people, and there is no known safety risk. However, the Kentucky Immunization Program recommends that providers counsel parents/guardians of children receiving either rotavirus vaccine about the presence of porcine circoviruses in the vaccines ***prior to administration*** in order to allow parents/guardians to make the most informed decision possible for their children. The rotavirus Vaccine Information Statement has been modified to include information about porcine circoviruses being in both vaccines.

The Kentucky Vaccine Program currently has both ROTARIX and RotaTeq vaccines available for order through the Vaccines for Children Program.

If you have questions regarding ordering, please contact the Kentucky Immunization Program at 502-564-4478. Clarissa Wilson is at extension 3734 (Clarissa.Wilson@ky.gov); Rita Lathrem is at extension 3914 (Rita.Lathrem@ky.gov); Judy Baker is at extension 3518 (Judy.Baker@ky.gov); and Laura Harrod is at extension 3855 (Laura.Harrod@ky.gov).

For nursing questions, including questions regarding the rotavirus vaccine schedules and intervals between doses, please call 502-564-4478. Melissa Eastman, RN is at extension 3334 (Melissa.Eastman@ky.gov); Nancy Hamilton, RN is at extension 3516 (Nancy.Hamilton@ky.gov); and Alicia Tindall, RN is at extension 3585 (Alicia.Tindall@ky.gov).

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